

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION)))) <hr/>	MDL NO. 1203
THIS DOCUMENT RELATES TO:))	
SHEILA BROWN, et al.)	
v.)	CIVIL ACTION NO. 99-20593
AMERICAN HOME PRODUCTS CORPORATION))	2:16 MD 1203

Bartle, C.J. February 26th, 2007

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Kenneth Patterson, Ms. Patterson's spouse, also has submitted a derivative claim for benefits.

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their

(continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. Part I of the Green Form is to be completed by the claimant or the claimant's representative. Part II is to be completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria in the Settlement Agreement. Finally, Part III is to be completed by the claimant's attorney if he or she is represented. To obtain Matrix Benefits, a claimant must establish that there is a reasonable medical basis for his or her claim under the criteria set forth in the Settlement Agreement. Accordingly, a claimant may not recover benefits if the attesting physician's reading of the echocardiogram, and thus his or her accompanying Green Form answers, have no reasonable medical basis.

3(...continued)

medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. and IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the other causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period, or who took the drugs for 60 days or less, or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these diet drugs.

In July 2002, claimant submitted a completed Green Form to the Trust signed by her attesting physician Reed Harris, D.O.⁴ Based on an echocardiogram dated February 8, 2002, Dr. Harris attested in Part II of her Green Form that she suffered from moderate mitral regurgitation and an abnormal left atrial dimension. Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of \$473,032.00.

In the report of claimant's echocardiogram, Dr. Harris stated that: "[t]he mitral regurgitant jet area to left atrial area is 20% consistent with moderate mitral regurgitation." Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22.

In December 2002, the Trust forwarded the claim at issue to Keith B. Churchwell, M.D., one of its auditing cardiologists, for review. In audit, Dr. Churchwell concluded that there was no reasonable medical basis for Dr. Harris' finding that claimant had moderate mitral regurgitation because her echocardiogram demonstrated only "[t]rivial to mild mitral regurgitation." Dr. Churchwell also determined that the "mitral

4. The Green Form reflects that claimant signed the Green Form in March 2002. The Green Form, however, was marked as "received" in July 2002.

regurgitant jet area [was] overestimated in comparison to LA size. <20%.”⁵ Dr. Churchwell did not contest the finding that claimant had an abnormal left atrial dimension.⁶

Thereafter, the Trust issued a post-audit determination denying Ms. Patterson’s claim.⁷ Pursuant to the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit (“Audit Policies and Procedures”), claimant contested this adverse determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; Pretrial Order (“PTO”) No. 2457, Audit Policies and Procedures § VI.⁸ The Trust

5. “LA” stands for Left Atrial.

6. Under the Settlement Agreement, a claimant is entitled to Level II Matrix Benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). As the Trust did not contest the attesting physician’s finding of an abnormal left atrial dimension, which is one of the conditions needed to qualify for a Level II claim, the only issue is claimant’s level of regurgitation.

7. Based on findings in audit, the Trust issues a post-audit determination regarding whether a claim is entitled to Matrix Benefits.

8. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in PTO No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Policies and Procedures contained in PTO No. 2457 apply to Ms. Patterson’s claim.

then applied to the court for issuance of an Order to show cause why Ms. Patterson's claim should be paid. On April 1, 2003, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 2815 (Apr. 1, 2003).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on June 19, 2003. Claimant submitted a Sur-Reply on July 3, 2003. The Show Cause Record is now before the court for final determination. See Audit Policies and Procedures § VI.O.

The issue presented for resolution of this claim is whether claimant has met her burden in proving that there is a reasonable medical basis for the attesting physician's finding that she had moderate mitral regurgitation.⁹ See id. at § VI.D. Ultimately, if we determine that there was no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must confirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. § VI.Q. If, on the other hand, we determine that there was a reasonable medical

9. Under the Settlement Agreement, moderate or greater mitral regurgitation is defined as a "regurgitant jet area in any apical view equal to or greater than twenty percent (20%) of the left atrial area (RJA/LAA)." Settlement Agreement § I.22.

basis, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id.

In support of her claim, claimant submitted a certification prepared by Frank Silvestry, M.D. Dr. Silvestry opined that:

I independently interpreted the study and performed my own measurements of the left atrial and regurgitant jet area. I identified the maximum regurgitant jet and measured its area using EchoAnalysis software. The jet I traced is an aliased Doppler jet emanating from the mitral valve in systole. The degree of mitral regurgitation is 20.57% with the maximal jet drawn at 1:15:38:12 recording time. . . . My tracing clearly shows that the mitral regurgitant jet was 4.47 cm², the left atrial area was 21.73 cm² . . . , and that Ms. Patterson has moderate (20.57%) mitral regurgitation as that term is defined in the Settlement Agreement.

As per Green Form appendix end notes #3 and #5, the maximal regurgitant jet is expressed as a percentage of the left atrial area. The auditing cardiologist does not contest the presence of Mitral regurgitation. The auditing cardiologist may be expressing his or her qualitative opinion of the degree of Mitral regurgitation; however, the Settlement documents specify a scientific and quantitative degree of mitral regurgitation, a degree which is clearly substantiated by the echocardiogram, and my independent measurements.

Claimant also argues in her show cause submissions that: (1) the standard for "no reasonable medical basis" should be a finding "that the conclusions of the Attesting Cardiologist are irrational, foolish, senseless, etc. from any medical

perspective;" (2) under the Settlement Agreement, the auditing cardiologist was required to provide a specific measurement as to the level of regurgitation; and (3) the requisite level of regurgitation need only be based on a maximum regurgitant jet.¹⁰

In finding that claimant suffered from only trivial to mild mitral regurgitation, the Trust's auditing cardiologist determined that the finding of moderate mitral regurgitation lacked a reasonable medical basis because the mitral regurgitant jet area was overestimated in relation to the left atrial area. Thus, claimant's level of mitral regurgitation was inflated. Improper measurements resulting in an inflated level of regurgitation, by definition, undermine the medical reasonableness of the attesting physician's conclusions. Claimant failed to rebut or challenge the conclusion that the attesting physician's conclusion was based on improper measurements. On this basis alone, claimant has failed to meet her burden of demonstrating that there is a reasonable medical basis for her claim.¹¹

10. Claimant also asserts that the requisite level of regurgitation can be determined simply by "an average from three planes" of the echocardiogram. This argument, however, need not be addressed because, as discussed infra, claimant's cardiologist relies on one maximum regurgitant jet to support his opinion, not an average from three planes of the echocardiogram.

11. We also disagree with claimant's definition of reasonable medical basis. Claimant relies on Gallagher v. Latrobe Brewing Co., 31 F.R.D. 36 (W.D. Pa. 1962) and Lesley v. Chie, 250 F.3d 47 (continued...)

Rather than address the specific deficiencies identified by the auditing cardiologist, claimant disagrees with the auditing cardiologist's conclusion and argues that measurement of her mitral regurgitation is required under the Settlement Agreement. Claimant also asserts that the mere fact that Drs. Harris and Churchwell disagreed regarding her level of regurgitation does not mean that Dr. Harris' answer to the Green Form question at issue lacked a reasonable medical basis. Finally, claimant argues that a single maximum measurement of the level of mitral regurgitation is sufficient to entitle her to Matrix Benefits. We disagree with claimant on all points.

First, we disagree with claimant's arguments concerning the required method for evaluating a claimant's level of valvular regurgitation. Although the Settlement Agreement specifies the percentage of regurgitation needed to qualify as having moderate mitral regurgitation, it does not specify that actual measurements must be made on an echocardiogram. As we explained in PTO No. 2640, "[e]yeballing' the regurgitant jet to assess

11(...continued)
(1st Cir. 2001), for determining what constitutes a reasonable medical basis. Such reliance, however, is misplaced. In Gallagher, the court addressed the situation of when a court would appoint an impartial expert witness to be presented to the jury. See Gallagher, 31 F.R.D. at 38. In Lesley, the court addressed a specific statutory framework under the Federal Rehabilitation Act concerning whether a physician's decision was discriminatory. See Lesley 250 F.3d at 52-57. We are not persuaded that these situations are even remotely analogous to the present case.

severity is well accepted in the world of cardiology." See PTO No. 2640 at 15 (Nov. 14, 2002).

While claimant relies on the Settlement Agreement's use of the word "measured" in the definition of "FDA Positive", its meaning must be considered in the context of the phrase "by an echocardiographic examination", which immediately follows it. See Settlement Agreement § I.22. In its entirety, the phrase placed at issue by claimant is "measured by an echocardiographic examination." The plain meaning of this phrase does not mean that actual measurements for assessing the level of mitral regurgitation are required. To the contrary, it means that a claimant's level of regurgitation must be determined based on an echocardiogram, as opposed to other diagnostic techniques. Claimant essentially requests that we write into the Settlement Agreement a requirement that actual measurements of mitral regurgitation be made to determine if a claimant qualifies for Matrix Benefits. There is no basis for such a revision and claimant's argument is contrary to the "eyeballing" standards we previously have evaluated and accepted in PTO No. 2640.

We believe this is particularly true in the context of Ms. Patterson's claim. The auditing cardiologist concluded that a review of claimant's echocardiogram revealed that the level of mitral regurgitation was overestimated. Under these

circumstances, visually estimating the level of claimant's mitral regurgitation is acceptable.

Second, the attesting physician's answer lacks a reasonable medical basis not because of a mere disagreement among cardiologists but because the attesting physician's finding failed to reflect the actual level of claimant's mitral regurgitation. We have previously found that conduct "beyond the bounds of medical reason" can include overtracing the amount of a claimant's regurgitation and characterizing "artifacts," "phantom jets," "backflow" and other low velocity flow as mitral regurgitation. See PTO No. 2640 at 15, 22. There simply is no "reasonable medical basis" for any conclusion of a cardiologist that is based on improper tracings, or any other conduct, that results in an inflated level of regurgitation. Id. Claimant's argument that "[t]here must be a reasonable medical basis for the finding of at least 20% MR [mitral regurgitation] if two out of three cardiologists are of that opinion" is not accepted. A claimant cannot establish a reasonable medical basis for his or her claim simply by supplying additional cardiologist opinions. This is especially true where, as here, claimant has failed to address the improper measurements underlying the finding of her attesting physician.

Finally, claimant suggests that a claimant may recover Matrix Benefits by the use of a single maximum measurement of the

level of mitral regurgitation. In support, claimant proffered the certification of Dr. Silvestry, who concluded, based on a single measurement of "the maximum regurgitant jet", that claimant had moderate mitral regurgitation. We do not accept this position. While one of the endnotes in the Green Form refers to obtaining the regurgitant jet area from a "maximum or average [of] three planes," this does not mean that a claim is compensable based only on the maximum or average regurgitant jet measured.

For a reasonable medical basis to exist, a claimant must establish that the findings of the requisite level of mitral regurgitation are representative of the level of regurgitation throughout the echocardiogram.¹² To conclude otherwise would allow claimants who do not have moderate or greater mitral regurgitation to receive Matrix Benefits, which would be contrary to the intent of the Settlement Agreement.¹³

12. Nothing in the Settlement Agreement suggests that it is permissible for a claimant to rely on isolated instances of what appears to be the requisite level of regurgitation to meet this definition.

13. In its show cause submissions, the Trust argues that, under Federal Rule of Civil Procedure 26(a)(2), physicians who proffer opinions regarding claims must disclose their compensation for reviewing claims and provide a list of cases in which they have served as experts. We disagree. While the Audit Policies and Procedures allow claimants to submit verified expert opinions in support of their claims, they do not require Rule 26(a)(2) disclosures. See Audit Policies and Procedures § VI.F. Discovery relating to claims is prohibited by the Audit Policies (continued...)

Moreover, we have previously stated that "[o]nly after reviewing multiple loops and still frames can a cardiologist reach a medically reasonable assessment as to whether the twenty percent threshold for moderate mitral regurgitation has been achieved.'" PTO No. 6897 (Jan. 26, 2007) (quoting PTO No. 2640 at 9). Claimant has not established that the "maximum regurgitant jet" offered in support of her claim is representative of her level of mitral regurgitation, therefore, on this basis as well, claimant has failed to establish a reasonable medical basis of her claim.

For the foregoing reasons, we conclude that claimant has not met her burden in proving that there is a reasonable medical basis for finding that she had moderate mitral regurgitation. Accordingly, we affirm the Trust's denial of Ms. Patterson's claim for Matrix Benefits and the related derivative claim submitted by her spouse.

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and Procedures. See id. § VII.A. Thus, requiring Rule 26(a)(2) disclosures in the show cause process would serve no purpose. Based on our disposition of the Trust's Rule 26 argument, claimant's motion to allow expert discovery is moot.

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

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PRETRIAL ORDER NO. _____

AND NOW, on this 26th day of February, 2007, for the reasons set forth in the accompanying Memorandum, it is hereby ORDERED that the final post-audit determination of the AHP Settlement Trust is AFFIRMED and the Level II Matrix claims submitted by claimant, Gay Patterson, and her spouse, Kenneth Patterson, are DENIED. It is further ORDERED that claimant Gay Patterson's Motion to Modify the Audit Procedures to Conform to the Trust's Recent Declaration that Discovery under the Federal Rules is Needed in Show Cause Proceedings is denied as moot.

BY THE COURT:

/s/ Harvey Bartle III
C.J.